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Docket No.: L7350.0011  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Toshihiro Nakajima et al.

Application No.: 10/592,918

Confirmation No.: n/a

Filed: September 15, 2006

Art Unit: n/a

For: PHARMACEUTICAL COMPOSITION  
CONTAINING hsHRD3

Examiner: not assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

**Timing of Filing of the Information Disclosure Statement:**

☒ This IDS is being filed before the First Office Action<sup>1</sup>.

<sup>1</sup> The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

- ☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action<sup>2</sup>.
- ☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee<sup>3</sup>.

**Certifications:**

If checked, the undersigned makes the following statement(s):

- ☐ Statement under 37 CFR § 1.97(e):

Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

- ☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application less than thirty days prior to the filing of this information disclosure statement.

**Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):**

- ☐ If checked, the fee of \$180.00 set forth in 37 C.F.R. §1.17(p) is attached.

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<sup>2</sup> The IDS *must* include *either* a certification under 37 C.F.R. §1.97(e) *or* the fee set forth in 37 C.F.R. §1.17(p).

<sup>3</sup> The IDS *must* include *both* a certification under 37 C.F.R. §1.97(e) *and* the fee set forth in 37 C.F.R. §1.17(p).

**Copies of Information:**

In accordance with 37 C.F.R. §1.98(a), the following is enclosed:

- ☒ A legible copy<sup>4</sup> of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.
- ☒ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:
  - ☐ A translation of the relevant portions of the non-English language information<sup>5</sup>;
  - ☐ A statement explaining the relevant portions of the non-English language information;
  - ☒ A copy [and, where not in the English language, a translation] of at least the relevant portion(s)<sup>6</sup> of the International Search Report for PCT/JP2005/005311 in which the information was cited; or
  - ☐ Information is contained in the specification of the present application for;
- ☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. , filed , which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

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<sup>4</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>5</sup> 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, “is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c).”

<sup>6</sup> The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which claims it applies, or merely an “X”, “Y”, or “A” indication on a search report. MPEP §609 III A(3).

**Materiality:**

Whether or not the information and references disclosed in this Information Disclosure Statement is “material” pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is “prior art” for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2215, under Order No. E3331.0417.

Dated: November 1, 2006

Respectfully submitted,

By 

Charles E. Miller

Registration No.: 24,576

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ALTERNATIVE TO PTO/SB/08A/B (09/06)

<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/592,918		
		Filing Date	September 15, 2006		
		First Named Inventor	Toshihiro Nakajima		
		Art Unit	N/A		
		Examiner Name	Not Yet Assigned		
Sheet	2	of	2	Attorney Docket Number	L7350.0011

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Cattaneo, M., et al.; Identification of a region within SEL1L protein required for tumour growth inhibition. Gene, 2004, 326, pages 149 to 156 (Disclosed are that tumour growth is inhibited by SEL1L having Hrd3 motif and that inhibiting action of tumour cell growth is weakened by deletion mutant of SEL1L)	
	CB	Amano, T., et al., Synoviolin/Hrd1, an E3 ubiquitin ligase, as a novel pathogenic factor for arthropathy., Genes & Development, 2003, 17, pgs. 2436 to 2449.	
	CC	Gardener, R.G., et al., Endoplasmic Reticulum Degradation Requires Lumen to Cytosol Signaling: Transmembrane Control of Hrd1p by Hrd3p., Journal of Cell Biology, 2000, 151(1), pgs. 69 to 82.	
	CD	Naoko Yagishita, et al., "Kansetsu Rheumatism Hassho no Byoin Bunshi Synoviolin", Igaku no Ayumi, 02 October 2004, 211(1), pgs. 124 to 128.	
	CE	Yagishita, N., et al., Essential Role of Synoviolin in Embryogenesis., Journal of Biological Chemistry, 2005, 280, pgs. 7909 to 7916.	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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ALTERNATIVE TO PTO/SB/08A/B (09/06)

<b>Substitute for form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/592,918
				Filing Date	September 15, 2006
				First Named Inventor	Toshihiro Nakajima
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	L7350.0011

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BA	WO-02/052007	07-04-2002	Locomogene, Inc.		
	BB	JP-2003-89647-A	03-28-2003	Takada Seiyaku Kabushiki Kaisha		
	BC	WO-2003/018033-A1	03-06-2003	The University of British Columbia		
	BD	JP-2002-10784-A	01-15-2002	Teijin Ltd.		
	BE	JP-2003-525243-A	08-26-2003	The University of British Columbia		
	BF	JP-7-324035-A	12-12-1995	LTT Institute Co., Ltd.		
	BG	JP-7-145062-A	06-06-1995	LTT Institute Co., Ltd.		
	BH	WO-01/76630-A1	10-18-2001	Kyowa Hakko Kogyo Kk et al.		
	BI	WO-01/21793-A1	03-29-2001	Miyasaka Nobuyuki et al.		
	BJ	WO-00/53194-A1	09-14-2000	Takata Seiyaku Co Ltd et al.		
	BK	JP-2001-503785-A	03-21-2004	Angiotech Pharmaceuticals, Inc.		
	BL	WO-00/38693-A1	07-06-2000	Toray Industries et al.		
	BM	WO-01/51480-A1	07-19-2001	Takara Shuzo Co et al.		
	BN	WO-01/95921-A1	12-20-2001	Gifu Shellac Mfg Co Ltd et al.		
	BO	WO-97/47622-A1	12-18-1997	Japan Tobacco Inc et al.		
	BP	JP-8-73453-A	03-19-1996	Otsuka Pharmaceutical Co., Ltd.		
	BQ	WO-99/28457-A1	06-10-1999	Otsuka Pharma Co Ltd et al.		
	BR	WO-2005/018675-A1	03-03-2005	Locomogene, Inc.		

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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